c. a preservative selected from the group consisting of diazolidinyl urea (DU), imidazolidinyl urea (IDU), an oxazolidine and mixtures thereof.

A5 cont'd D1

40. (New) A reagent composition for preparing leukocytes for cytometric analysis, comprising:

a. a high density lipoprotein;

b. an agent for lysing erythrocytes in a sample of fresh blood for permitting cytometric analysis of said leukocytes; and

c. diazolidinyl urea (DU).

Remarks

Applicants would like to thank Examiner Thuy Nguyen for the courtesies extended to the undersigned in an interview on June 20, 2001. Applicants appreciate the respect shown by Examiner Nguyen in assuming responsibility for meeting with the undersigned after learning that Examiner McCaa had left the USPTO between the time of scheduling the interview and the date of the interview.[1] In view of the unusual circumstances of this file transfer, and the indication of Examiner Nguyen at the interview that she was uncertain that responsibility for this file would ultimately be transferred to her, Applicants respectfully request that the Examiner presently responsible for the file contact the undersigned by telephone at the earliest convenience in the event a further rejection of the claims is made. Applicant would like to avoid any unnecessary delay in the issuance of this application occasioned by the departure of Examiner McCaa.

Foremost, Applicants affirm the election with traverse as set forth in the Office Action.

As was discussed at the interview, Applicants have presented claims to clarify the inventive concepts embraced by the present claims. Foremost, though

[1] Examiner McCaa neglected to contact the undersigned to advise of the departure or to postpone the interview. Thus, Examiner Nguyen graciously contacted the undersigned on or about June 19, 2001 in an effort to accommodate the undersigned while the undersigned was visiting the USPTO that trip.

Applicants disagree with the Examiner's rejections under 35 U.S.C. Section 112, Applicants have amended the claims by either correcting typographicals or removing surplus verbiage. Accordingly, the rejections are believed to be overcome.

As for the rejections under 35 U.S.C. 102 and 103, Applicants respectfully traverse. First, as discussed at the interview, the Young '933 patent (which is primarily directed to a simulated whole blood control) and the Ledis '206 patent both fail to teach or suggest, inter alia, the use of a combination of lipoprotein and the particular preservatives recited in Applicants' claims for use in a flow cytometer system. The Ryan '208 patent, though addressing compositions useful as simulated whole blood controls in a hematology instrument such as a flow cytometer, does not teach or suggest the specific combination of ingredients now recited in Applicants' claims. Likewise, the Ryan '099 patent is directed to a preservative generally and does not address the specific claimed combination either.

As a result, there is an absence of any motivation (except through impermissible hindsight analysis) to combine any of the above references to arrive at Applicants' claimed invention. To the extent the references teach lipoprotein at all, they are directed to controls that simulate whole blood, they do not address a composition that includes a lysing agent for lysing erythrocytes from a fresh blood sample, as there is no need for it. In short, the present claims amply distinguish over the art of record, and the rejections should be withdrawn.

Regarding the specification, the Examiner has objected to the drawing description. The Examiner appears to have ignored the drawing discussion in the Examples. In view of the discussion (see, e.g., Page 8), no further amendment is needed. Withdrawal of the objection is requested.

The Examiner indicates that informal drawings were filed. Applicants' file indicates that formal drawings have been submitted. To the extent the Examiner persists in this objection, Applicants request that it be held in abeyance until the claims are allowed.

Conclusions

In view of Applicant's amendments and remarks, the Examiner's rejections are believed to be rendered moot. Accordingly, Applicant submits that the present application is in condition for allowance and requests that the Examiner pass the case to issue at the earliest convenience. Should the Examiner have any question or wish to further discuss this application, Applicant requests that the Examiner contact the undersigned at (248) 593-9900.

If for some reason Applicant has not requested a sufficient extension and/or have not paid a sufficient fee for this response and/or for the extension necessary to prevent the abandonment of this application, please consider this as a request for an extension for the required time period and/or authorization to charge our Deposit Account No. 50-1097 for any fee which may be due.

Respectfully submitted,

Dated: July 9, 2001

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Once Amended) A reagent composition for preparing leukocytes for cytometric analysis, comprising:

a. a lipoprotein; [and]

d. an agent for lysing erythrocytes <u>from a sample of fresh blood</u> for permitting cytometric analysis of said leukocytes<u>; and</u>

e. <u>a preservative selected from the group consisting of diazolidinyl urea (DU), imidazolidinyl urea (IDU), an oxazolidine and mixtures thereof.</u>

5. (Once Amended) A system for flow cytometry, comprising:

a. a flow cytometer instrument;

b. a reagent for preparing leukocytes for analysis by flow cytometry, said reagent including:

iv. <u>a lipoprotein;</u>

v. <u>an agent for lysing erythrocytes for permitting cytometric analysis of said leukocytes; and</u>

vi. <u>a preservative selected from the group consisting of diazolidinyl urea (DU), imidazolidinyl urea (IDU), an oxazolidine and mixtures thereof.</u>

[i. an effective amount of a lipoprotein; and

ii. an effective amount of a lytic agent.]

9. (Once Amended) The composition of claim 1 further comprising [an effective amount of] a physiologically compatible salt.

35. (Once Amended) The system of claim 5 further comprising a sample preparation instrument <u>for preparing a whole blood sample for flow cytometric analysis</u>.

36. (Once Amended) The system of claim 5 further comprising an antibody for binding with a surface [antogen] antigen of at least one of said leukocytes.

Please add new claims 39 and 40:

39. (New) A reagent composition for preparing leukocytes for cytometric analysis, comprising:

a. a high density lipoprotein;

d. an agent for lysing erythrocytes in a sample of fresh blood for permitting cytometric analysis of said leukocytes; and

e. a preservative selected from the group consisting of diazolidinyl urea (DU), imidazolidinyl urea (IDU), an oxazolidine and mixtures thereof.

40. (New) A reagent composition for preparing leukocytes for cytometric analysis, comprising:

d. a high density lipoprotein;

e. an agent for lysing erythrocytes in a sample of fresh blood for permitting cytometric analysis of said leukocytes; and

f. diazolidinyl urea (DU).